

### **REMARKS**

This Amendment is in reply to the Final Office Action mailed May 5, 2004, for which an unextended response is due August 5, 2004. Claims 1-21 and 24-26 are currently pending in the instant application. Claims 18 and 20 have been cancelled, without prejudice. Applicants respectfully reserve the right to pursue the subject matter of cancelled claims herein in a future continuing application. Claims 1, 19 and 21 are currently amended in order to advance prosecution on the merits. No new matter has been added.

Claim 1 has been amended to state that the claimed cells are intended for the production of human helper dependent adenoviral vectors containing a first and second genic unit as further described in said claim. Thus, the first genic unit comprises a human adenovirus defective genome having inverted terminal repeats in a head-to-toe configuration, an inactivated encapsidation signal, and at least one of the adenoviral non-structural regions inactivated; and the second genic unit comprises at least one inducible promoter and at least one of the human adenoviral regions inactivated in the first genic unit. Support for this amendment can be found on page 13, lines 35-37, to page 14, lines 1-6, of the specification.

Claims 18 and 20 have been canceled. Claims 19 and 21 have been amended to more specifically delineate the composition of the first and second genic units, respectively. Currently amended claim 19 states that the adenovirus defective genome of the first genic unit is either totally or partially derived from a human adenovirus selected from the group consisting of Ad2 and Ad5. Similarly, currently amended claim 21 states that the viral regions of the second genic unit, said viral regions representing those absent from the adenovirus defective genome of the first genic unit, are totally or partially derived from a human adenovirus selected from the group consisting of Ad2 and Ad5. Support for this amendment can be found on page 13, lines 35-37, to page 14, lines 1-6, of the specification.

Applicants request that the above amendments to the claims be entered. Any omission of subject matter by amendment of the claims is done without prejudice to pursuing the same in a continuation or divisional application.

### **Rejection of Claims 1 and 18-21 under 35 U.S.C. §112, ¶2**

Claims 1 and 18-21 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite due to the recitation of the phrase "totally or partially constituted" in description of the first or second genic unit. It is stated that while "[c]laims 18-21 require the addition of a human adenovirus where the adenovirus 'totally or partially constitute' presumably the activity of

the first genetic unit, . . . [it] is not clear if the human adenovirus includes or excludes a complete human adenovirus for the purpose of 'totally or partially constituted.'" Applicants respectfully traverse.

While Applicants maintain that one of ordinary skill in the art could readily appreciate how much of either the first or second genic units could be comprised of sequences from a single adenovirus species (e.g., human adenovirus sequences) or serotype (e.g., human Ad5 sequences), Applicants have canceled claims 18 and 20, and have amended claims 19 and 21, in order to advance prosecution on the merits. These claim cancellations and amendments are done without prejudice to pursuing, in a separate application, any subject matter canceled or omitted hereby. Claim 19 has been amended to state that the human adenovirus defective genome of the first genic unit described in newly amended claim 1, comprising inverted terminal repeats, an inactivated encapsidation signal, and at least one of the non-structural regions inactivated, is either totally or partially derived from human Ad2 or human Ad5. Thus, at least one of the components of the human adenovirus defective genome of the first genic unit, and up to all of the components of said defective genome, may be derived from human Ad2 or human Ad5 sequences. It is important to remember, however, that said first genic unit still comprises a defective adenovirus genome; and thus, those sequences of either human Ad2 or human Ad5 included within the first genic unit could not represent the entire human Ad2 or Ad5 genome, respectively. Similarly, claim 21 has been amended to state that the viral regions of the second genic unit are totally or partially derived from human Ad2 or human Ad5.

Accordingly, Applicants respectfully request the reconsideration of the instant rejection.

**Rejection of Claims 1-21 and 24-26 under 35 U.S.C. §112, ¶1**

Claims 1-21 and 24-26 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to enable one of ordinary skill in the art to practice the invention commensurate in scope with the cited claims. The instant enablement rejection states that the specification, "while being enabling for using human adenoviral vectors and cell lines expressing human adenoviral constructs, does not reasonably provide enablement for adenoviruses derived from other species." Applicants respectfully traverses.

While Applicants maintain that is within the expertise of one skilled in the art, especially considering the information known in the art at the time of the invention, to identify those adenoviral components which may need to be supplied by the helper cells via the introduced genic units in order to provide complementing activity, Applicants have amended the claims in order to advance prosecution on the merits. Specifically, claim 1 has been amended to recite that

the claimed cells are intended for the production of human helper dependent adenoviral vectors, wherein the first genic unit comprises a human adenovirus defective genome. As the remainder of the claims either directly or indirectly depends upon claim 1, Applicants assert that the claims currently reflect subject matter deemed allowable by the Examiner in the Final Office Action. Any omission of subject matter by amendment of the claims is done without prejudice to pursuing the same in a continuation or divisional application.

Applicants, therefore, respectfully request the reconsideration and withdrawal of the instant rejection.

In view of the amendments and comments herein, Applicants respectfully take the position that claims 1-17, 19, 21 and 24-26 are in proper form for allowance and a favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned attorney if clarification is required on any aspect of this response, or if any of the claims are considered to require further amendment to be placed in condition for allowance after entry of this response.

Respectfully submitted,

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